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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,897	04/02/1999	KATSUMI AOYAGI	4047	1769

7590 12/31/2003

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/269,897	AOYAGI ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4,11,12,34,37,38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4,11,34,37,38 and 41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 4,11,12,34,37,38 and 41 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-9-2003 has been entered.

The amendment filed on 9-29-2003 is acknowledged. Claims 11, 37 and 41 have been amended. Claims 4, 11, 34, 37-38 and 41 are currently under examination.

This application contains claim 12 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection should have included cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The non-initialed references cited on the information disclosure statements filed on 9-11-2002 and 2-5-2003 have, as yet, not become available and hence have not been considered.

Claim Rejections Withdrawn

Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “comprising at least one of urea and an imidazole ring-containing compound or a indole ring containing compound” is withdrawn. Upon further consideration the prior amendment to the claim is deemed sufficient to overcome the rejection.

The rejection of claims 11, 37 and 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by method step (2) is withdrawn in light of the amendment thereto.

The rejection of claims 4, 11, 34, 37, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma (WO 92/19285) in view of Kokai (Japanese Patent Abstract No. 53-104724 – IDS-4) and Cloyd et al. (U.S. Patent 6,074,646) is withdrawn.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to methods of detecting HCV or HBV in a biological sample by treating said sample with a “treatment solution” wherein said “treatment solution” inactivates antibodies present in the sample (see step 2 of claimed methods). Said sample is then subjected to an

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immunoassay that utilizes an antibody probe wherein said immunoassay is performed "in the presence" of said "treatment solution". It should be noted that the term "in the presence" is considered vague and indefinite (see below) and is being interpreted to mean that the antibody probe is added to the sample comprising the "treatment solution" and the "exposed" viral antigen. The specification gives no guidance as to what combination of components, if any, would result in a treatment solution that would inactivate the endogenous antibodies present in the biological sample (step 2 of the claimed methods) but not inactivate the antibody probe subsequently used in the immunoassay (step 3 of the claimed methods). The specification is equally silent on which antibody probes, if any, would be impervious to the inactivating properties of the claimed "treatment solution". While the skill in the art of immunology and protein chemistry is high, one of skill in the art would not be able to contemplate what combination of treatment solution components and antibody probe would meet the limitations of the claimed methods since the antibody probe (which must remain functional in order to be used to detect viral antigens in the immunoassay) and the endogenous antibodies (which must be inactivated) are exposed to the identical conditions. Since, one of skill in the art would expect any solution that inactivated the endogenous antibodies present in the sample to also inactivate any antibody probe, he/she would not be able to make the treatment solution needed to perform the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 37 and 41 are rendered vague and indefinite by method steps (1) and (2). The wording of said method step is confusing since said steps are not linked by claim language. It is unclear whether the “treated virus-containing sample” of step (2) is the end product of step (1).

Claims 11, 37 and 41 are rendered vague and indefinite by the use of the term “in the presence of”. It is unclear what is the claimed role of the treatment solution. Is Applicant claiming that the immunoassay is performed in the treatment solution (i.e. the antibody probe is added to the end product of step 2)? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 4 is rendered vague and indefinite since it is dependent on a canceled claim (claims 31).

Claim 34 is rendered vague and indefinite since it is dependent on a canceled claim (claims 32).

Claim 38 is rendered vague and indefinite since it is dependent on a canceled claim (claims 33).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Lynette R. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1645

Robert A. Zeman
December 22, 2003